UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456
	)	Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO:	)	Subcategory No. 07-11618-PBS
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., Civil Action No. 07-11618-PBS	)	Hon. Patti B. Saris

RESPONSE OF RELATOR VEN-A-CARE OF THE FLORIDA KEYS, INC. TO ABBOTT'S MOTION TO DISMISS

The Relator, Ven-A-Care of the Florida Keys, Inc. (hereinafter "Ven-A-Care" or "VAC"), files this response to the Defendant Abbott's Motion to Dismiss[1] pursuant to Federal Rule of Civil Procedure 12b(1) wherein Abbott alleges this Court lacks subject matter jurisdiction under the False Claims Act's Public Disclosure Bar as set forth at 31 U.S.C. § 3730 (e) (4). This case involves Abbott's Pharmaceutical Products Division and that division's erythromycin drugs (the "Erys")

I.

Background and Context

To prevent unnecessarily duplicative briefing Ven-a-Care incorporates, by reference, the entirety of its Combined Response to Motions to Dismiss Filed by Abbott, Dey and Roxane (Docket # _____) (to be filed concurrently as of this 11/2/09 filing date), along with all supporting evidence, being filed today in connection with this Combined Response; specifically including, but not limited to, the Public Disclosure analysis and showing of Original Source proof encompassing information underlying this "Ery" litigation. (See Jones Affidavit ¶¶ 22-24 w/ related Exh. 7.) Ven-a-Care also incorporates its Opposition to Abbott's (Ery) Motion for Partial Summary Judgment (Docket # 6621) and its Response to Abbott's related Statement of Facts in support (Docket # 6622) because Abbott confuses the record by also injecting Public Disclosure issues into those filings.

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[1] This Court has granted leave for Ven-A-Care to file a combined response to the Defendants' motions. MDL No. 1456; Master File No. 01-12257-PBS; Subcategory Case No. 06-11337; Docket No. 6583-2; October 15, 2009 Order on Consent Motion to Modify Briefing Schedule and Consolidate Opposition to Defendants' Motions to Dismiss Into One Memorandum of Law.

II.

Materials cited specifically by Abbott in this Ery case are not Public Disclosures

The False Claims Act case at issue involves fraudulent drug pricing representations by Abbott which created mega-spreads on a specific line of Abbott Pharmaceutical Products Division oral medications known as the Ery drugs. Due to Abbott's unique concealment of transaction prices and publication of inflated prices, these mega-spreads caused Medicaid reimbursement for Abbott's Ery drugs to be higher than it would have been if Abbott had caused lower prices to be published. (See VAC SOF in support of VAC MPSJ (docket # 6417) ¶¶ 7-9, 14-15, and 17-19; *see also* VAC Response to Abbott MPSJ SOF at Duggan Declaration ¶ 33.)

Abbott cites to a few specific items of information which were not previously addressed in the other Motions to Dismiss filed against Ven-a-Care by Dey, Roxane and Abbott or Ven-a-Care's Combined Response to such. Ven-a-Care only addresses these incremental alleged Public Disclosures as raised by Abbott. Ven-a-Care presents these arguments in connection with its related legal briefing and proof filed contemporaneously in its Combined Response.

Abbott MTD Exhibit No. 2 (1984 OIG report)

This document does not name Abbott, does not name any specifically-identified "Abbott" NDC, and does not make any allegation of fraud. Rather than make an allegation of fraud or of mega-spreads described by this Court, the OIG found that "of the 3,469 drug purchases that we examined . . . 3,455 (99.6 percent) – were made at prices averaging about 16 percent below AWP." (See Abbott MTD Exh. 2 at p. 10,193.) This finding of a small percentage discrepancy contrasts markedly with Ven-a-Care specific

claims against Abbott regarding the Ery drugs because Ven-a-Care's alleged spreads are far larger. For instance, Ven-a-Care alleges spreads which equate to discounts from the misleading published WAC of approximately 40% and higher. (See VAC SOF (docket # 6622) ¶ 3 and VAC SOF Anderson Dec. Exh. 2 - 2/15/01 Complaint ¶ 84-85.) These discounts from WAC result in much larger discounts from AWP because AWP is 25% higher than WAC for these Abbott products. (See VAC Memo in Support of MPSJ (docket #6423) at p. 4 and VAC Ery SOF ¶ 14). This so-called disclosure does not provide either the "X" and the "Y" together, or the "Z" of Ven-a-Care's allegations as required under *Springfield Railroad*. *Actavis*, 2009 U.S. Dist. Lexis 92945 at *9 (*quoting West*, 538 F.Supp. 2d at 383 *(quoting United States ex rel. Springfield Terminal Ry. Co. v. Quinn*, 14 F.3d 645, 654 (D.C. Cir. 1994) (citations omitted)

Abbott notes that "EES" was shown as a drug for which pricing data was gathered. Abbott also submits a deficient affidavit to support its position that such a reference adequately identified Abbott as the maker of that erythromycin. (See Abbott Exh. 1.) Ven-a-Care objects to this affidavit. Rather than providing personal knowledge, the affidavit presents rank speculation about the affiant's belief of mysterious others' thoughts. Additionally, the speculation is focused upon others who "are knowledgeable of the pharmaceutical markets". (See Abbott Exh. 1.) Abbott presents no authority that such a specified group constitutes the "public" for purposes of a public disclosure under the FCA. Even if this mention of "EES" was sufficient to identify Abbott, the spreads which are noted (a discount of approximately 24% off of AWP) are still less than the discounts Ven-a-Care alleged when couched in those terms. Ven-a-Care alleges specific Ery spreads which equate to discounts from the misleading published WAC of

approximately 40% and higher. (See 2/15/01 Complaint ¶ 84-85). These discounts from WAC result in much larger discounts from AWP because AWP is 25% higher than WAC for these Abbott products. (See VAC MPSJ p. 4 and VAC Ery SOF ¶ 14). This so-called disclosure does not provide either the "X" and the "Y" together, or the "Z" of Ven-a-Care's allegations as required under *Springfield Railroad*. *Actavis*, 2009 U.S. Dist. Lexis 92945 at *9 (*quoting West*, 538 F.Supp. 2d at 383 *(quoting United States ex rel. Springfield Terminal Ry. Co. v. Quinn*, 14 F.3d 645, 654 (D.C. Cir. 1994) (citations omitted)

Also, in this report the OIG noted "HCFA has periodically supplied State Medicaid agencies with invoice price level data designed to assist them in evaluating their Estimated Acquisition Cost (EAC) limits. However, the data supplied has not been an adequate substitute for AWP and may have been counterproductive since the amounts furnished have often been very similar to the AWP for individual drugs. The statistics gathered by HCFA are based on drug prices shown on invoices. These prices are generally list prices and do not reflect any . . . discounts." (emphasis added) (See Abbott MTD Exh. 2 at p. 10,193.) This OIG information is inconclusive and confusing as to the extent of discounts from AWP and certainly did not present any allegations of fraud or misrepresentation.

Abbott MTD Exhibit No. 3 (9/17/86 letter from CO Medicaid to HCFA)

This correspondence does not fit within one of the enumerated statutory descriptions of a public disclosure. "For the jurisdictional bar . . . to apply, an 'allegation or transaction' must have been publicly disclosed in one of the sources explicitly

identified by the statute. *West*, 538 F.Supp.2d at 376; citing, *U.S. ex rel. LeBlanc v. Raytheon Co.*, 913 F.2d 17, 20 (1st Cir. 1990). Also, it is a letter which does not name Abbott or any other drug company; nor does it provide any drug pricing information on specific products. In fact, it does not even distinguish between pricing of brand drugs and generic drugs. While the document does provide a statement about a marketing "tool" of "generic companies", the reference would not in anyway identify Abbott. Abbott has made no showing it is known as a generic company. In fact, Abbott is widely known as a brand drug company rather than a generics manufacturer. Abbott's CEO touts that Abbott is a "broad-based medical innovator" which seeks to continue to "advance medical science . . . through our products" and also that Abbott sets their "sights on pioneering solutions that advance health care." (See Anderson Dec. Exh. 1.)

Abbott MTD Exhibit 6 (May 1, 1989 Drug Store News article)

This document is a niche market publication rather than a widely-distributed news media article available to the public. To the contrary, an internet search reveals the magazine claims to be the "voice of the retail drug industry." The article does not publicly disclose any information or allegations regarding pricing fraud. To the contrary, the article seems to dispute some drug companies' arguments in AWP pricing cases that pharmacies needed AWP-based reimbursement spreads. Instead, the author notes "AWP doesn't stand for 'Average Wholesale Price' anymore, it really stands for 'Against the Working Pharmacist.'" (See Abbott MTD Exh. 6 at p. 3.) Ven-a-Care's alleges Abbott manipulated published Ery pricing which caused pharmacies to receive Medicaid drug reimbursements far in excess of pharmacies' general drug acquisition costs. It is hard to

see how excessive drug reimbursements as alleged by Ven-a-Care were "against the working pharmacist." This article does not constitute a public disclosure of Ven-a-Care's transactions or allegations. In fact, it seems to contradict them.

Abbott MTD Exhibit 7 (July 24, 1989 Pink Sheet article)

As addressed by Ven-a-Care in the Combined Response and for the reasons noted immediately above, this article does not qualify as a "news media" item under the FCA precedent. Furthermore, this document does not discuss Abbott or Ery drugs in any manner. It actually is focused upon brand drugs although it does mention aggregate brand and generic prices. The document describes unrelated issues surrounding federal Veteran's Administration pricing which involves the federal government's purchase of drugs for dispensation. (See Abbott MTD Exh. 7 at p. 1.) This role of the federal government is completely different that the role of state Medicaid programs in reimbursing retail pharmacies for dispensing drugs to Medicaid patients. A retail pharmacy has only a miniscule fraction of the bargaining power of the federal government in actually buying drugs.

Abbott MTD Exhibit 8 (Feb. 12, 1989 Philadelphia Inquirer article)

This article does not mention Abbott or Ery pricing in any manner whatsoever. It confusingly sets forth information from a national chain drugstore company which claims drug reimbursement at AWP less 10% would cause them to lose money ($.84) on each prescription filed. (See Abbott MTD Exh. 8 at p. 5). This hardly seems to indicate

mega-spreads on AWPs of any drug, much less Abbott's Erys, and cannot be argued to have "put the government on the trail" of Abbott's Ery fraud.

Abbott MTD Exhibit 9 (July 18, 1989 Congressional hearing)

This document does not mention drug pricing fraud of any sort and certainly does not name Abbott or provide any Ery drug pricing information. Instead, The Chairman of the U.S. Senate Special Committee on Aging, Hon. David Pryor, stated "(w)hen it comes to boasting of their profits to Wall Street, the drug companies can be heard loud and clear, but they are awfully quiet when it comes to discussing the prices they charge on Main Street." (See Abbott MTD Exh. 9 at p. 4). Abbott cites this document for the unremarkable proposition that the Acting Administrator of HCFA stated studies showed "average wholesale price for drugs overstates the actual prices paid by as much as 10 to 20 percent." *Id*. at p. 6. As noted above repeatedly, Ven-a-Care did not allege fraud regarding the expected AWP mark-up and such a statement by HCFA did not "set the government on the trail" of the unique Ery pricing fraud pled by Ven-a-Care.

Abbott MTD Exhibit No.11 (July 31, 1992 Congressional committee on Energy and Commerce hearing)

Abbott falsely cites its misleadingly incomplete Abbott MTD Exh. 11 (also marked as Abbott SOF Exh. 16) for the proposition that the National Association of Retail Druggists ("NARD") "submitted a comparison of the contract prices (available to members of its organization) and published AWPs." (See Abbott SOF ¶ 29.) This is untrue. NARD was saying the opposite – that its members retail pharmacies could not

receive the contract prices presented.[2] NARD did not provide prices, titled "Prucare" prices, to Congress to show that retail pharmacies were receiving low prices. To the contrary, these Prucare prices were represented to be "hospital prices." (See Anderson Dec. to SOF in support of Response to MSPJ Exh. 9 at p. 295 and 298.) NARD's point was that only non-retail pharmacies such as hospitals, HMOs, and mail order, for instance, were getting discounts beyond 15% off of AWP. *Id.* at p. 286, 295 and 301. The full version of the July 1992 Congressional record shows NARD was presenting the low prices as "hospital" prices which "were discounted beyond the amount (AWP-15%) that might be available to retail pharmacists." *Id.* at p. 295 and 301. NARD continued in stating, "(a)ny way you slice it our members are getting a raw deal." *Id.* NARD's members were retail pharmacies. NARD absolutely did not indicate retail pharmacies were buying drugs at low contract prices.

Relatedly, PruCare appears to be connected with an insurance company which is likely operating, at least in part, as a Health Maintenance Organization ("HMO"). (See Anderson Dec. Exh. 2.) HMO pricing or other non-pharmacy pricing reveals nothing about the retail pharmacy pricing upon which Ven-a-Care's allegations were founded and which Ven-a-Care brought forward to the government regarding Ery. HMOs are able to maintain closed formularies thereby exerting bargaining power in their negotiation of drug prices. (See Abbott MTD Exhibit 7 pp. 2-3). Medicaid programs instead operate open formularies and do not possess such bargaining power.

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[2] NARD represented "40,000 independent pharmacies" responsible for "nearly 85% of the Medicaid pharmaceutical services". (See VAC SOF Response - Anderson Dec. Exh.9 - July 1992 Congressional record p. 280.)

Lastly, this document fails to mention Abbott by name or by NDC labeler code. While the document does mention a drug initial or abbreviation, it does not provide any explicit information to the public regarding the name of the drug or, just as importantly, the manufacturer. Abbott's proffered affidavit of an Abbott employee attempts to salvage Abbott's argument by somehow magically making the document mean more on its face than it does. The affidavit fails. First, Abbott has presented no precedent for the premise that specific external evidence, such as this affidavit, can somehow make a document a public disclosure. Second, the affidavit itself is defective. The affiant cannot possibly have personal knowledge about what "those knowledgeable of the pharmaceutical market" know and understand. (See Abbott MTD Exh. 1.) The affiant instead presents speculation as a mind-reader. Further, Abbott makes no showing, because it can't, that the persons referenced in the affidavit as "those knowledgeable of the pharmaceutical market" somehow constitute the public within the context of FCA public disclosure law. In fact, given how doggedly the pharmaceutical manufacturer, wholesaler and pharmacy sectors of the industry try to keep prices secret, the persons who are "knowledgeable of the pharmaceutical market" are a very rare breed.

Abbott MTD Exhibit No. 13 (March 20, 1997 "Record of Discussion"

This short memo purports to record a meeting apparently involving nine (9) people who worked for different state's Medicaid programs. This does not meet any of the enumerated categories for a public disclosure under the FCA. "For the jurisdictional bar . . . to apply, an 'allegation or transaction' must have been publicly disclosed in one of the sources explicitly identified by the statute. *West*, 538 F.Supp.2d at 376; citing,

U.S. ex rel. LeBlanc v. Raytheon Co., 913 F.2d 17, 20 (1st Cir. 1990). The document also does not mention Abbott in anyway nor does it set forth any pricing data or spread information. The document only notes an expectation that AWPs be about 20% greater than retail pharmacy prices. (See Abbott MTD Exh. 13 at p. 3). Such information is not a disclosure of Ven-a-Care's allegations of much larger spreads on specific drugs.

Abbott MTD Exhibit No. 14 (Aug. 1997 OIG report)

This document does not mention Abbott by name or by NDC labeler code and Abbott admits such. (See Abbott Memo p. 6). In its Memo, Abbott tries to avoid this uncomfortable truth by stating, "there can be no doubt" this report included Erys. Id. Abbott does not cite any proof for this proposition other than to claim the following MTD Exhibit 15 constitutes the work papers for this report cited as MTD Exhibit 14. Ven-a-Care has shown in its Combined Response and related proof that it provided pricing data which underlies this report.

Abbott MTD Exhibit No. 15 (voluminous collection of papers)

These papers are purported by Abbott to be work papers related to MTD Exh. 14. Ven-a-Care does not have any information this proposition is true and Abbott has not made this showing. These unknown papers do not meet any of the enumerated categories for a public disclosure under the FCA. "For the jurisdictional bar . . . to apply, an 'allegation or transaction' must have been publicly disclosed in one of the sources explicitly identified by the statute. *West*, 538 F.Supp.2d at 376; citing, *U.S. ex rel. LeBlanc v. Raytheon Co.*, 913 F.2d 17, 20 (1st Cir. 1990). Furthermore, even if oral

medication pricing was listed such would not put the "government on the trail of fraud" because no such allegation of fraud was being made and no specific allegation as to Abbott or, for that matter, every single maker of erythromycin (and there were many) was committing AWP fraud.

Abbott MTD Exhibit 16 (1998 study of Idaho Medicaid reimbursement)

The drug pricing information shown in the document only pertains to Idaho drug reimbursement. (See Exh. 16 p. 1). The Idaho Medicaid reimbursements are then compared against only drug prices derived from 52 pharmacies located in Kentucky and Arkansas. Id. Courts have held that state reports such as this do not constitute a public disclosure. In holding "only federal" reports are to be considered a FCA public disclosure the Fourth Circuit stated,

> "Because the federal government is unlikely to learn about state and local investigations, a large number of fraudulent claims against the government would go unremedied without the financial incentives offered by the qui tam provisions of the FCA. If the public-disclosure bar were to encompass investigations and reports at the state and local level, as the defendants contend, the effect would be to discourage private actions that the federal government is not capable of pursuing on its own."
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> *U.S. ex rel Wilson v. Graham Co. Soil and Water Conservation Dist.*, 528 F.3d 292, 306 (4th. Cir. 2008).

Not that any additional discussion is necessary regarding this state-level document, but this document also does not set forth any claims of fraud or implication of wrongdoing. This document does not provide any allegations fraud against Abbott or otherwise. While this is the rare document which actually mentions an Abbott Ery product (in this instance through the reference to a specific NDC number), this document does not provide the necessary "Z" and does not constitute a FCA "public disclosure." It

is also worth noting that some overall pricing data revealed by this study actually shows average discounts from AWP to be only about 16% (or the mathematical inverse of a standard 20% markup from a real WAC to generate an AWP). (See Abbott MTD Exh. 16 at "Exhibit B"). This information indicates drugs are not purchased at large discounts from AWP and certainly does not indicate mega-spreads. Finally, there has been no showing this document was ever made public.

Abbott MTD Exhibit 17 (1999 study of Wyoming Medicaid reimbursement)

This document fails to qualify as a public disclosure under the FCA for the same reasons and precedent set forth immediately above. Also, this state-specific study is not sufficiently available and too limited in scope or information to provide any meaningful information regarding Ery, or otherwise, which puts the government onto the trail of any fraud.

Abbott MTD Exhibit 18 (May 1998 OIG report)

This report pertains to the subject of Medicaid rebates which is not pertinent to drug manufacturer pricing manipulation and misrepresentation. The report does not breathe a word regarding Abbott, Ery pricing, or even the generalized idea of AWP misconduct or fraud. Instead the report simply refers to a need to establish a "connection between the calculation of Medicaid drug rebates, and the calculation of Medicaid's reimbursement for drugs at the pharmacy level." (See Abbott MTD Exh. 18 at p. 2). Also, the report is focused upon brand drugs and notes brand drug price increases. Id. at p. 10. Of course, such brand drug pricing information did nothing to put the "government

on the trail" of Ery brand drug pricing fraud by Abbott PPD because it fraudulently priced those drugs differently than its other brands. (See Ven-a-Care's Response to Abbott's MPSJ with SOF and exhibits – Docket #s 6621 and 6622.)

III.

Conclusion

Abbott's specific Motion to Dismiss Ven-a-Care's claims against Abbott concerning Ery drugs for lack of subject-matter jurisdiction should be denied. No FCA "public disclosure" of Ven-a-Care's Ery claims occurred prior to Ven-a-Care filing its Ery claims on February 15, 2001. Furthermore, even if this Court were to find such a public disclosure, Ven-a-Care has clearly evidenced it is an Original Source of the information underlying its allegations concerning Ery.[3]

[3] See Combined Response to related Motions to Dismiss raising identical and virtually identical issues.

Respectfully submitted,

Dated: November 2, 2009

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CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above "RESPONSE TO MOTION FOR DISMISS" to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Jarrett Anderson

Dated: November 2, 2009